

Claims

1. A *Clostridium difficile* lactate dehydrogenase comprising the amino acid sequence of SEQ ID NO: 2, or an amino acid sequence exhibiting at least 70, 80, 90, 95, 5 96, 97, 98, 99, or 99.5% identity with the amino acid sequence of SEQ ID NO: 2.
2. An isolated nucleic acid molecule encoding the *Clostridium difficile* lactate dehydrogenase as claimed in claim 1.
- 10 3. An isolated nucleic acid molecule according to claim 2, comprising the nucleotide sequence of SEQ ID NO: 1.
4. A nucleic acid vector comprising the nucleic acid molecule of either one of claims claim 2 or 3.
- 15 5. A host cell containing the vector of claim 4.
6. A process for producing a polypeptide comprising the *Clostridium difficile* lactate dehydrogenase according to claim 1, the process comprising culturing the host cell 20 of claim 5 under conditions sufficient for the production of said polypeptide, and recovering said polypeptide.
7. A vector according to claim 4, wherein said vector is selected from the group consisting of a plasmid, a virus, and a bacteriophage.
- 25 8. A vector according to claim 7, wherein said isolated nucleic acid molecule is inserted into said vector in proper orientation and correct reading frame such that a polypeptide comprising the *Clostridium difficile* lactate dehydrogenase may be expressed by a cell transformed with said vector.

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9. A vector according to claim 8, wherein said isolated nucleic acid molecule is operatively linked to a promoter sequence.

10. An antibody or an antigen-binding fragment thereof specific against a
5 *Clostridium difficile* lactate dehydrogenase according to claim 1.

11. An antibody or an antigen-binding fragment thereof according to claim 10 for use in a method of treatment or diagnosis of the human or animal body.

10 12. A method of manufacture of a medicament for the treatment of a *Clostridium difficile* infection, comprising the use of an antibody or an antigen-binding fragment thereof according to claim 10.

15 13. A medicament, comprising a therapeutically effective quantity of an antibiotic and an antibody or an antigen-binding fragment thereof specific against a *Clostridium difficile* lactate dehydrogenase according to claim 1.

14. A medicament according to claim 13 for use in a method of treatment or diagnosis of the human or animal body.

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15. A medicament according to claim 13, being for the treatment of a *Clostridium difficile* infection.

25 16. A method of manufacture of a medicament for the treatment of a *Clostridium difficile* infection, characterised in the use of a therapeutically effective quantity of an antibiotic and an antibody or an antigen-binding fragment thereof specific against a *Clostridium difficile* lactate dehydrogenase according to claim 1.

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17. A method of treatment of *Clostridium difficile* infection, comprising the step of administering to a patient in need of same a therapeutically effective quantity of an antibiotic and an antibody or an antigen-binding fragment thereof specific against a *Clostridium difficile* lactate dehydrogenase according to claim 1.

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18. A diagnostic test method for detecting the presence in a sample of a *Clostridium difficile* lactate dehydrogenase according to claim 1, comprising the steps of:

10 i) contacting said sample with an antibody or an antigen-binding fragment thereof specific against said *Clostridium difficile* lactate dehydrogenase;

15 ii) detecting any antibody-antigen binding reaction; and

iii) correlating the results of detection step (ii) with the presence of said *Clostridium difficile* lactate dehydrogenase in said sample.

19. A diagnostic test method for detecting the presence in a sample of antibody specific against a *Clostridium difficile* lactate dehydrogenase according to claim 1
20 comprising the steps of:

25 i) contacting said sample with said *Clostridium difficile* lactate dehydrogenase;

ii) detecting any antibody-antigen binding reaction; and

iii) correlating the results of detection step (ii) with the presence of antibody specific against said *Clostridium difficile* lactate dehydrogenase in said sample.

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20. A diagnostic test method according to either one of claims 18 or 19, the sample being a sample from a patient.
21. A diagnostic test kit for performing a diagnostic test method according to any 5 one of claims 18-20.
22. A pharmaceutical pack for the treatment of a *Clostridium difficile* infection, comprising a therapeutically effective quantity of an antibiotic and an antibody or an antigen-binding fragment thereof specific against a *Clostridium difficile* lactate 10 dehydrogenase according to claim 1.
23. A medicament, method of manufacture, method of treatment, diagnostic test method, diagnostic test kit, or pharmaceutical pack according to any one of claims 12-22, said antibiotic being vancomycin, ramoplanin, teicoplanin, or metronidazole. 15
24. A medicament, method of manufacture, method of treatment, diagnostic test method, diagnostic test kit, or pharmaceutical pack according to any one of claims 12-22, said infection being due to *Clostridium difficile*.
- 20 25. A medicament, method of manufacture, method of treatment, diagnostic test method, diagnostic test kit, or pharmaceutical pack according to any one of claims 12-22, said bacterium being resistant to treatment by said antibiotic alone.